

The following specification amendments were submitted with the original filing. However, when initially submitted Applicant filed the Japanese version of the originally filed PCT amendment along with a direct translation of the Japanese amendment. Therefore, the amendment was not in proper US application amendment format.

Applicant now submits a clarified version of the original translation. Therefore, please preliminarily amend the paragraphs of the originally submitted specification as follows:

SUMMARY OF THE INVENTION

[0001] In order to resolve the problems raised above, the method of designing and manufacturing the artificial stem with the use of the composite materials relating to this invention is configured to ~~provide the structure of the method of designing and manufacturing the artificial stem with the use of the composite material, which is comprised of a first external layer, which is inserted and fixed in an insertion hole formed in a bone without filling cement, torsional stiffness thereof is increased as contacting an internal surface of said insertion hole; a main structure layer, which is positioned in an inner side than said first external layer, bending stiffness thereof is increased; a core layer with lower stiffness than the main structure layer and the first external layer, which is positioned in an inner side than said main structure layer; and a most inner layer, which is positioned between the core layer and the main structure layer, wherein the method comprises~~ steps of performing, as using a computer, an analysis involving an internal stress of the artificial joint stem and an adhesive stress of the artificial joint stem and a bone based on three dimension data indicating a structure of the bone made by using plural bone tomographic images and a design condition involving a form and stiffness of the artificial joint stem configured at least by one of the tomographic images and the three dimension image; having the computer to reanalyze as changing the design condition if a result of the analysis fails to satisfy the design condition;

designing and manufacturing the artificial joint stem using stem data based on the result of the analysis and the design condition if the result of the analysis satisfies the design condition.

[0002] ~~The method of designing and manufacturing the artificial joint stem with uses composite materials regarding this invention may be structured such that an external form of an epiphysis approximately fitting an internal form of an insertion hole formed in said bone, said artificial joint stem has a main part with stiffness around a boundary between epiphysis and diaphysis varies so as to lower the stiffness as approaching the diaphysis and a neck to place a spherical head in the artificial joint thereon.~~

[0003] ~~The method of designing and manufacturing artificial joint stem with the use of composite material further comprising~~ “Also, the artificial joint stem may further comprise a guide section, which may be provided at the tip of the main part and placed at the diaphysis, where the guide section has a lower bending and stretching/tensile stiffness than the main part.”

[0004] According to ~~the invention this~~, the guide section is provided in the forefront of the stem, and as a result, the stem can be easily inserted in the insertion hole during the operation when inserting the stem into the insertion hole penetrated into bone because the stem's insertion is guided by the guide section.

[0005] Also, since the bending and tensile stiffness of the guide section is made lower than the main part, the stress applied to the connecting section between the guide section and bone can be less than the main part. To explain in detail, this ~~invention stem~~, as having the same structure of the example in FIG. 24D, the stress concentration at the ends of the connecting section between the stem's main part and bone can be controlled, and may

prevent the stem from getting loose due to the stem's separation from bone. Also, the stem's loading is transferred from the guide section to bone via the main part, thus for the femur, for example, it is the proximal fixing and the stem's loading can be well transferred to bone. Furthermore, also at the guide section, the stress shielding can be controlled for bone contacting the guide section, since the compression stress is equally applied.

[0006] The method of designing and manufacturing artificial joint stem with the use of composite material in the invention can also have a composition that "~~the computer performs the finite element method may be used to perform~~ analysis including the internal stress of the bone ~~by using a finite element method.~~" Here, the finite element method is a known structure analysis method wherein the subject for analysis is broken down into simple shape-elements such as triangle and rectangular and the respective element is calculated to perform analysis. Furthermore, as shown in FIG. 16, because the internal bone system is not uniform, for example, the analysis may be performed as allocating the predetermined number per element according to the density, and the respective value can be automatically allocated by the predetermined method.

[0007] According to this invention, the stress analysis is performed by using the finite element, and therefore, time necessary for analysis can significantly be shortened and the result of the analysis can become closest possible to the characteristics of the actual bone, thereby increasing the reliability of the analysis result.

[0008] The method of designing and manufacturing artificial joint stem with the use of composite material in the invention can also have a structure that "the tomographic image is a tomographic image, which is obtained by different transmission speed of the layers of the bone, and further comprising a step of analyzing the internal stress of the bone as determining the Young's modulus and the density of every element of the bone based on the relation of the predetermined density and Young's modulus of the bone and the transmission

speed”

[0009] The method of designing and manufacturing artificial joint stem with the use of composite material in the invention can also have a structure of forming as superposing the composite materials of the first external layer, the main structure layer, and the core layer by molding in a die.